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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability MDL NO. 15-02641-PHX-DGC
Litigation

This Document Relates to:

MARY DUFFIE and JAMES DUFFIE,

Plaintiffs,

CASE NO. CV-15-2093-PHX-DGC

v.

C. R. BARD, INC., a New Jersey
Corporation; and BARD PERIPHERAL
VASCULAR INC., (a subsidiary and/or
division of defendant C. R. BARD, INC.)
an Arizona Corporation,

**DEFENDANTS C. R. BARD, INC. AND
BARD PERIPHERAL VASCULAR,
INC.'S ANSWER AND DEFENSES TO
PLAINTIFFS' COMPLAINT AND
DEMAND FOR TRIAL BY JURY**

Defendants.

Defendants C. R. Bard, Inc. (“Bard”) and Bard Peripheral Vascular, Inc. (“BPV”) (collectively “Defendants”), through undersigned counsel, hereby answer the Complaint as follows:

1. Defendants admit that Plaintiffs have brought this civil action for damages but deny that Plaintiffs have suffered any personal injuries caused by Defendants, deny that Defendants are liable to Plaintiffs, and deny that Plaintiffs are entitled to any damages from Defendants.

PARTIES, JURISDICTION, AND VENUE

2. Defendants are without knowledge or information sufficient to admit or deny the allegations contained in Paragraph 2 of Plaintiffs’ Complaint and, on that basis, deny them.

3. Defendants admit that Bard is a New Jersey Corporation and that Bard is authorized to do business, and does business, in the State of Georgia. Defendants admit that Bard owns a facility where vena cava filters are manufactured, including filters under the trademark G2® Filter System. Bard denies any remaining allegations contained in Paragraph 3 of Plaintiffs’ Complaint including any allegations contained in footnote 1 of the Plaintiffs’ Complaint.

4. Defendants admit that BPV is an Arizona Corporation and that BPV is authorized to do business, and does business, in the State of Georgia. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants further admit that BPV is a wholly owned subsidiary of Bard. Defendants deny any remaining allegations contained in Paragraph 4 of the Complaint.

JURISDICTION AND VENUE

5. Defendants do not contest that the injuries and damages alleged within Plaintiffs’ Complaint exceed the jurisdictional limit of this Court. However, Defendants deny that they are liable to Plaintiffs for any amount whatsoever and deny that Plaintiffs have

suffered any damages whatsoever. Defendants do not dispute that, based on the facts as alleged by Plaintiffs, which have not been and could not have been confirmed by Defendants, this Court appears to have jurisdiction over this dispute.

6. Defendants admit that the Judicial Panel of Multidistrict Litigation recently consolidated certain claims related to Bard IVC filters into MDL No. 2461, the venue for which is the United States District Court for the District of Arizona and over which Judge David Campbell presides.

GENERAL BACKGROUND ALLEGATIONS

7. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff Mary Duffie and, on that basis, deny them. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 7 of Plaintiffs' Complaint.

8. Defendants admit that Bard owns a facility where vena cava filters are manufactured. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademark G2® Filter Systems. Defendants further admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants deny any remaining allegations contained in Paragraph 8 of Plaintiffs' Complaint.

9. Defendants deny the allegations contained in Paragraph 9 of Plaintiffs' Complaint, including all subparts thereof.

IVC FILTERS GENERALLY

10. Defendants lack knowledge or information sufficient to admit or deny the allegation regarding the trademark on any product at issue in this case. Defendants admit that Bard owns a facility where vena cava filters are manufactured (including filters under the trademark G2® Filter System) and further admit that BPV designs, sells, markets, and

1 distributes inferior vena cava filters (including filters under the trademark G2® Filter
2 System). Defendants further admit that the G2® Filter System has been marketed, sold, and
3 distributed since September 2005. Defendants deny any remaining allegations contained in
4 Paragraph 10 of Plaintiffs' Complaint.

5 11. Defendants lack knowledge or information sufficient to admit or deny the
6 allegation regarding the time frame when inferior vena cava filters were first introduced on
7 the market or the identity of manufacturers of inferior vena cava filters. Defendants deny any
8 remaining allegations of Paragraph 11 of Plaintiffs' Complaint.

9 12. Defendants admit that inferior vena cava filters are intended to prevent injury or
10 death resulting from venous thrombosis and pulmonary embolism. Defendants further admit
11 that inferior vena cava filters may be designed for permanent placement, temporary
12 placement, or both. Defendants deny any remaining allegations of Paragraph 12 of Plaintiffs'
13 Complaint.

14 13. Defendants admit that the inferior vena cava is a large vein that receives blood
15 from the lower regions of the body and delivers it to the right atrium of the heart. Defendants
16 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to
17 human health, including sometimes death. Defendants deny any remaining allegations of
18 Paragraph 13 of Plaintiffs' Complaint.

19 14. Defendants admit that certain people are at an increased risk for the
20 development of deep vein thrombosis and pulmonary embolus, but lack sufficient information
21 to admit or deny the allegations regarding the various risk factors which may predispose an
22 individual to deep vein thrombosis or pulmonary emboli and thus deny them. Defendants
23 deny any remaining allegations of Paragraph 14 of Plaintiffs' Complaint.

24 15. Defendants admit that patients at a high risk for developing deep vein
25 thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy,
26 including but not limited to the medications listed in Paragraph 15 of Plaintiffs' Complaint.
27 Defendants further admit that inferior vena cava filters may also be used to treat patients who
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1 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants
2 lack knowledge or information sufficient to admit or deny any remaining allegations
3 contained in Paragraph 15 of Plaintiffs' Complaint and, on that basis, deny them.

4 16. Defendants lack knowledge or information sufficient to admit or deny the
5 allegation regarding the time frame when inferior vena cava filters were first introduced on
6 the market. Defendants deny any remaining allegations of Paragraph 16 of Plaintiffs'
7 Complaint.

8 17. Defendants lack knowledge or information sufficient to admit or deny the
9 allegations regarding the medical community's concerns regarding the desirability of a
10 retrievable filter or the intent of manufacturers in general regarding the development of
11 retrievable filters. Defendants deny any remaining allegations of Paragraph 17 of Plaintiffs'
12 Complaint, including any allegations contained in footnote 2 of the Plaintiffs' Complaint.

13 18. Defendants admit that a nickel-titanium alloy named Nitinol is used in the
14 manufacture of the G2® Filter. Defendants admit that Nitinol contains shape memory.
15 Defendants lack knowledge or information sufficient to admit or deny the allegations as to the
16 development or other uses of Nitinol. Defendants deny any remaining allegations of
17 Paragraph 18 of Plaintiffs' Complaint.

18 19. Defendants admit that Bard previously designed, manufactured, and sold a
19 device named the Recovery® Filter System. Defendants deny the remaining allegations of
20 Paragraph 19 of Plaintiffs' Complaint.

21 20. Defendants deny the Recovery® Filter System was unreasonably dangerous or
22 defective in any manner. Defendants admit that there are various well-documented
23 complications that may occur as a result of the fracture and/or migration of any inferior vena
24 cava filter. Defendants further admit that it is well-documented that many instances of filter
25 fracture and/or migration result in no complications whatsoever, but, rather, are completely
26 asymptomatic. By way of further response, Defendants state that there are incidents related
27 to the occurrence of known complications associated with every manufacturer of inferior
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1 vena cava filters. Defendants deny the remaining allegations of Paragraph 20 of Plaintiffs'
2 Complaint.

3 21. Defendants deny the Recovery® Filter System was unreasonably dangerous or
4 defective in any manner. Defendants state that there are incidents related to the occurrence of
5 known complications associated with every manufacturer of inferior vena cava filters.
6 Defendants deny any remaining allegations contained in Paragraph 21 of the Plaintiffs'
7 Complaint.

8 22. Defendants deny the Recovery® Filter System was unreasonably dangerous or
9 defective in any manner. Defendants deny the remaining allegations contained in
10 Paragraph 22 of the Plaintiffs' Complaint, including any allegations contained in footnote 3
11 of the Plaintiffs' Complaint.

12 23. Defendants admit that, as part of their continuing efforts to constantly evaluate
13 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
14 continually striving to improve the life-saving performance of those devices. The G2® Filter
15 was developed in furtherance of those efforts. Defendants deny the remaining allegations
16 contained in Paragraph 23 of Plaintiffs' Complaint.

17 24. Defendants admit the G2® Filter System was cleared by the United States Food
18 and Drug Administration pursuant to an application submitted under Section 510(k) of the
19 Food, Drug and Cosmetic Act in 2005. The allegations pertaining to the requirements of
20 Section 510(k) are legal conclusions of law to which no answer is required. Defendants deny
21 any remaining allegations contained in Paragraph 24 of Plaintiffs' Complaint.

22 25. Defendants admit that the G2® Filter was originally cleared by the FDA for
23 permanent use. Defendants further admit that the G2® Filter was subsequently cleared by the
24 FDA for optional use as a retrievable inferior vena cava filter. Defendants deny any
25 remaining allegations contained in Paragraph 25 of Plaintiffs' Complaint.

26 26. Defendants admit that both the Recovery® Filter and the G2® Filter have a
27 similar design, consisting of twelve, shape-memory Nitinol wires emanating from a central
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1 Nitinol sleeve. Defendants further admit that, in both devices, the twelve wires form two
2 levels of filtration for emboli: the legs provide the lower level of filtration, and the arms
3 provide the upper level of filtration. Defendants deny any remaining allegations of
4 Paragraph 26 of Plaintiffs' Complaint.

5 27. Defendants admit that both the Recovery® Filter and the G2® Filter are made
6 of Nitinol. Defendants deny any remaining allegations of Paragraph 27 of Plaintiffs'
7 Complaint.

8 28. Defendants admit that the G2® Filter was designed to be inserted
9 endovascularly. Defendants further admit that the G2® Filter is designed to be delivered via
10 an introducer sheath, which is included in the delivery system for the device. Defendants
11 deny any remaining allegations of Paragraph 28 of Plaintiffs' Complaint.

12 29. Defendants lack knowledge or information sufficient to admit or deny the
13 allegations contained in Paragraph 29 of the Plaintiffs' Complaint regarding the "typical"
14 practices of physicians, and on that basis, such allegations are denied. Defendants deny any
15 remaining allegations of Paragraph 29 of the Plaintiffs' Complaint.

16 30. Defendants deny the allegations contained in Paragraph 30 of the Plaintiffs'
17 Complaint.

18 31. Defendants deny the allegations contained in Paragraph 31 of the Plaintiffs'
19 Complaint.

20 32. Defendants admit that, as part of their continuing efforts to constantly evaluate
21 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
22 continually striving to improve the life-saving performance of those devices. The G2® Filter
23 was developed in furtherance of those efforts. Defendants deny any remaining allegations of
24 Paragraph 32 of the Plaintiffs' Complaint, including any allegations contained in footnote 4
25 of the Plaintiffs' Complaint.

26 33. Defendant Bard admits that it periodically receives notice of incidents involving
27 a device it manufactured and, when appropriate, Bard reports such incidents to the United
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1 States Food and Drug Administration (“FDA”). By way of further response, Bard states that
2 there are incidents related to the occurrence of known complications associated with every
3 manufacturer of vena cava filters. Defendants deny the remaining allegations of
4 Paragraph 33 of the Plaintiffs’ Complaint.

5 34. Defendants admit that there are various well-documented complications that
6 may occur as the result of the fracture and/or migration of any inferior vena cava filter. Bard
7 states that there are incidents related to the occurrence of known complications associated
8 with every manufacturer of inferior vena cava filters. By way of further response, Bard states
9 that information available in the public domain, including the FDA MAUDE database, is not
10 a comprehensive analysis of all instances of such complications. Defendants deny the
11 remaining allegations of Paragraph 34 of Plaintiffs’ Complaint.

12 35. Defendants admit that there are various well-documented complications that
13 may occur as the result of the fracture and/or migration of any inferior vena cava filter.
14 Defendants state that there are incidents related to the occurrence of known complications
15 associated with every manufacturer of inferior vena cava filters. By way of further response,
16 Defendants state that information available in the public domain, including the FDA MAUDE
17 database, is not a comprehensive analysis of all instances of such complications. Defendants
18 deny the remaining allegations of Paragraph 35 of Plaintiffs’ Complaint, including all sub-
19 parts thereof.

20 36. Defendants admit that there are various well-documented complications that
21 may occur as a result of the fracture and/or migration of any inferior vena cava filter.
22 Defendants further admit that it is well documented than many instances of filter fracture
23 and/or migration result in no complications whatsoever but, rather, are completely
24 asymptomatic. By way of further response, Bard states that there are incidents related to the
25 occurrence of known complications associated with every manufacturer of inferior vena cava
26 filters. Defendants deny the remaining allegations of Paragraph 36 of the Plaintiffs’
27 Complaint, including all sub-parts thereof.

37. Defendants deny the allegations of Paragraph 37 of the Plaintiffs' Complaint.

38. Defendants deny the allegations of Paragraph 38 of the Plaintiffs' Complaint.

39. Defendants admit that, in the course of his very limited study, Dr. Hull makes certain recommendations regarding patient and physician follow-up of Recovery® Filters. Defendants deny the G2® Filter is unreasonably dangerous or defective in any manner. Defendants deny the remaining allegations of Paragraph 39 of the Plaintiffs' Complaint, including the allegations contained in footnote 5.

40. Defendants admit that cardiac catheterization is one means of identifying struts that have fractured. Defendants deny the remaining allegations of Paragraph 40 of the Plaintiffs' Complaint.

41. Defendants admit that CT scanning, cardiac catheterization, filter removal, and/or surgical intervention are some of the ways in which a physician may treat struts that have fractured. Defendants deny the remaining allegations of Paragraph 41 of the Plaintiffs' Complaint, including all sub-parts thereof.

42. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff Mary Duffie and, on that basis, denies them. Defendants deny the remaining allegations contained in Paragraph 42 of Plaintiffs' Complaint.

43. Defendants deny the allegations of Paragraph 43 of the Plaintiffs' Complaint.

44. Defendants deny the allegations of Paragraph 44 of the Plaintiffs' Complaint.

45. Defendants deny the allegations contained in Paragraph 45 of the Plaintiffs' Complaint, including all sub-parts thereof.

46. Defendants deny the allegations contained in Paragraph 46 of the Plaintiffs' Complaint.

47. Defendants deny the allegations contained in Paragraph 47 of the Plaintiffs' Complaint.

1 48. Bard admits that on August 9, 2010, the Food and Drug Administration posted
2 an initial communication titled “Inferior Vena Cava (IVC) Filters: Initial Communication:
3 Risk of Adverse Events with Long Term Use,” and that Initial Communication stated that
4 “Since 2005, the FDA has received 921 device adverse event reports involving IVC filters.”
5 However, to the extent Paragraph 48 purports to cast liability either directly or indirectly
6 upon Defendants, said Paragraph is expressly denied.

7 49. Defendants deny the allegations contained in Paragraph 49 of the Plaintiffs’
8 Complaint.

9 50. Defendants deny the allegations contained in Paragraph 50 of the Plaintiffs’
10 Complaint, including all subparts thereof.

11 51. Defendants deny the allegations contained in Paragraph 51 of the Plaintiffs’
12 Complaint.

13 52. Defendants deny the allegations contained in Paragraph 52 of the Plaintiffs’
14 Complaint.

15 53. In response to the allegations contained in Paragraph 53, Bard admits only that
16 the regulation cited in Paragraph 53 exists. To the extent the allegations in Paragraph 53 of
17 Plaintiffs’ Complaint purport to cast liability upon Defendants, either directly or indirectly,
18 those allegations are denied.

19 54. In response to the allegations contained in Paragraph 54, Bard admits only that
20 the regulation cited in Paragraph 54 exists. To the extent the allegations in Paragraph 54 of
21 Plaintiffs’ Complaint purport to cast liability upon Defendants, either directly or indirectly,
22 those allegations are denied.

23 55. In response to the allegations contained in Paragraph 55, Bard admits only that
24 the regulation cited in Paragraph 55 exists. To the extent the allegations in Paragraph 55 of
25 Plaintiffs’ Complaint purport to cast liability upon Defendants, either directly or indirectly,
26 those allegations are denied.

1 56. The allegations contained in Paragraph 56 of Plaintiffs' Complaint are
2 conclusions of law, which require no response. To the extent a response is required,
3 Defendants deny those allegations.

4 57. In response to the allegations contained in Paragraph 57, Bard admits only that
5 the statute cited in Paragraph 57 exists. To the extent the allegations in Paragraph 57 of
6 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
7 those allegations are denied.

8 58. In response to the allegations contained in Paragraph 58, Bard admits only that
9 the statute cited in Paragraph 58 exists. To the extent the allegations in Paragraph 58 of
10 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
11 those allegations are denied.

12 59. In response to the allegations contained in Paragraph 59, Bard admits only that
13 the statute cited in Paragraph 59 exists. To the extent the allegations in Paragraph 59 of
14 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
15 those allegations are denied.

16 60. In response to the allegations contained in Paragraph 60, Bard admits only that
17 the regulation cited in Paragraph 60 exists. To the extent the allegations in Paragraph 60 of
18 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
19 those allegations are denied.

20 61. In response to the allegations contained in Paragraph 61, Bard admits only that
21 the regulation cited in Paragraph 61 exists. To the extent the allegations in Paragraph 61 of
22 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
23 those allegations are denied.

24 62. In response to the allegations contained in Paragraph 62, Bard admits only that
25 the regulation cited in Paragraph 62 exists. To the extent the allegations in Paragraph 62 of
26 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
27 those allegations are denied.
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1 63. In response to the allegations contained in Paragraph 63, Bard admits only that
2 the regulation cited in Paragraph 63 exists. To the extent the allegations in Paragraph 63 of
3 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
4 those allegations are denied.

5 64. In response to the allegations contained in Paragraph 64, Bard admits only that
6 the regulation cited in Paragraph 64 exists. To the extent the allegations in Paragraph 64 of
7 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
8 those allegations are denied.

9 65. In response to the allegations contained in Paragraph 65, Bard admits only that
10 the regulation cited in Paragraph 65 exists. To the extent the allegations in Paragraph 65 of
11 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
12 those allegations are denied.

13 66. In response to the allegations contained in Paragraph 66, Bard admits only that
14 the regulation cited in Paragraph 66 exists. To the extent the allegations in Paragraph 66 of
15 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
16 those allegations are denied.

17 67. In response to the allegations contained in Paragraph 67, Bard admits only that
18 the regulation cited in Paragraph 67 exists. To the extent the allegations in Paragraph 67 of
19 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
20 those allegations are denied.

21 68. In response to the allegations contained in Paragraph 68, Bard admits only that
22 the regulation cited in Paragraph 68 exists. To the extent the allegations in Paragraph 68 of
23 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
24 those allegations are denied.

25 69. In response to the allegations contained in Paragraph 69, Bard admits only that
26 the regulation cited in Paragraph 69 exists. To the extent the allegations in Paragraph 69 of
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1 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
2 those allegations are denied.

3 70. In response to the allegations contained in Paragraph 70, Bard admits only that
4 the regulation cited in Paragraph 70 exists. To the extent the allegations in Paragraph 70 of
5 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
6 those allegations are denied.

7 71. In response to the allegations contained in Paragraph 71, Bard admits only that
8 the regulation cited in Paragraph 71 exists. To the extent the allegations in Paragraph 71 of
9 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
10 those allegations are denied.

11 72. In response to the allegations contained in Paragraph 72, Bard admits only that
12 the regulation cited in Paragraph 72 exists. To the extent the allegations in Paragraph 72 of
13 the Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or
14 indirectly, those allegations are denied.

15 73. In response to the allegations contained in Paragraph 73, Bard admits only that
16 the regulation cited in Paragraph 73 exists. To the extent the allegations in Paragraph 73 of
17 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
18 those allegations are denied.

19 74. In response to the allegations contained in Paragraph 74, Bard admits only that
20 the regulation cited in Paragraph 74 exists. To the extent the allegations in Paragraph 74 of
21 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
22 those allegations are denied.

23 75. In response to the allegations contained in Paragraph 75, Bard admits only that
24 the regulation cited in Paragraph 75 exists. To the extent the allegations in Paragraph 75 of
25 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
26 those allegations are denied.

1 76. In response to the allegations contained in Paragraph 76, Bard admits only that
2 the regulation cited in Paragraph 76 exists. To the extent the allegations in Paragraph 76 of
3 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
4 those allegations are denied.

5 77. In response to the allegations contained in Paragraph 77, Bard admits only that
6 the regulation cited in Paragraph 77 exists. To the extent the allegations in Paragraph 77 of
7 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
8 those allegations are denied, including all subparts thereof.

9 78. In response to the allegations contained in Paragraph 78, Bard admits only that
10 the regulation cited in Paragraph 78 exists. To the extent the allegations in Paragraph 78 of
11 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
12 those allegations are denied.

13 79. In response to the allegations contained in Paragraph 79, Bard admits only that
14 the regulation cited in Paragraph 79 exists. To the extent the allegations in Paragraph 79 of
15 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
16 those allegations are denied.

17 80. In response to the allegations contained in Paragraph 80, Bard admits only that
18 the regulation cited in Paragraph 80 exists. To the extent the allegations in Paragraph 80 of
19 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
20 those allegations are denied.

21 81. In response to the allegations contained in Paragraph 81, Bard admits only that
22 the regulation cited in Paragraph 81 exists. To the extent the allegations in Paragraph 81 of
23 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
24 those allegations are denied, including all sub-parts thereof.

25 82. In response to the allegations contained in Paragraph 82, Bard admits only that
26 the regulation cited in Paragraph 82 exists. To the extent the allegations in Paragraph 82 of
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1 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
2 those allegations are denied.

3 83. In response to the allegations contained in Paragraph 83, Bard admits only that
4 the regulation cited in Paragraph 83 exists. To the extent the allegations in Paragraph 83 of
5 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
6 those allegations are denied.

7 84. In response to the allegations contained in Paragraph 84, Bard admits only that
8 the regulation cited in Paragraph 84 exists. To the extent the allegations in Paragraph 84 of
9 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
10 those allegations are denied.

11 85. In response to the allegations contained in Paragraph 85, Bard admits only that
12 the regulation cited in Paragraph 85 exists. To the extent the allegations in Paragraph 85 of
13 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
14 those allegations are denied.

15 86. In response to the allegations contained in Paragraph 86, Bard admits only that
16 the regulation cited in Paragraph 86 exists. To the extent the allegations in Paragraph 86 of
17 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
18 those allegations are denied.

19 87. In response to the allegations contained in Paragraph 87, Bard admits only that
20 the regulation cited in Paragraph 87 exists. To the extent the allegations in Paragraph 87 of
21 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
22 those allegations are denied.

23 88. In response to the allegations contained in Paragraph 88, Bard admits only that
24 the regulation cited in Paragraph 88 exists. To the extent the allegations in Paragraph 88 of
25 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
26 those allegations are denied, including all sub-parts thereof.

1 89. Defendants admit the G2® Filter System was cleared by the United States Food
2 and Drug Administration pursuant to an application submitted under Section 510(k) of the
3 Food, Drug and Cosmetic Act in 2005. Defendants deny any remaining allegations contained
4 in Paragraph 89 of Plaintiffs' Complaint.

5 90. Defendants admit the G2® Filter System was cleared by the United States Food
6 and Drug Administration pursuant to an application submitted under Section 510(k) of the
7 Food, Drug and Cosmetic Act in 2005. Defendants deny any remaining allegations contained
8 in Paragraph 90 of Plaintiffs' Complaint.

9 91. Defendants deny the allegations contained in Paragraph 91 of Plaintiffs'
10 Complaint.

11 92. Defendants deny the allegations contained in Paragraph 92 of Plaintiffs'
12 Complaint.

13 93. Defendants deny the allegations contained in Paragraph 93 of Plaintiffs'
14 Complaint.

15 94. Defendants deny the allegations contained in Paragraph 94 of Plaintiffs'
16 Complaint.

17 95. Defendants deny the allegations contained in Paragraph 95 of Plaintiffs'
18 Complaint.

19 96. Defendants deny the allegations contained in Paragraph 96 of Plaintiffs'
20 Complaint.

21 **FRAUDULENT CONCEALMENT**

22 97. Defendants deny the allegations contained in Paragraph 97 of Plaintiffs'
23 Complaint.

24 98. Defendants deny the allegations contained in Paragraph 98 of Plaintiffs'
25 Complaint.

26 99. Defendants deny the allegations contained in Paragraph 99 of Plaintiffs'
27 Complaint.

CORPORATE/VICARIOUS LIABILITY

100. Defendants deny the allegations contained in Paragraph 100 of Plaintiffs' Complaint.

101. Defendants deny the allegations contained in Paragraph 101 of Plaintiffs' Complaint.

102. Defendants deny the allegations contained in Paragraph 102 of Plaintiffs' Complaint.

103. Defendants deny the allegations contained in Paragraph 103 of Plaintiffs' Complaint.

FIRST CAUSE OF ACTION

NEGLIGENCE

104. Defendants incorporate by reference their responses to Paragraphs 1-103 of Plaintiffs' Complaint as if fully set forth herein.

105. Defendants deny the allegations of Paragraph 105 of Plaintiffs' Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants deny any remaining allegations contained in Paragraph 105 of Plaintiffs' Complaint.

106. Defendants are without information or knowledge sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff Mary Duffie and, on that basis, deny them. Defendants deny any remaining allegations contained in Paragraph 106 of Plaintiffs' Complaint.

107. The allegations contained in Paragraph 107 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required,

1 Defendants deny the allegations. Defendants deny the remaining allegations contained in
2 Paragraph 107 of Plaintiffs' Complaint.

3 108. Defendants deny the allegations contained in Paragraph 108 of Plaintiffs'
4 Complaint.

5 109. Defendants deny the allegations contained in Paragraph 109 of Plaintiffs'
6 Complaint, including all sub-parts thereof.

7 110. Defendants deny the allegations contained in Paragraph 110 of Plaintiffs'
8 Complaint.

9 111. Defendants deny the allegations contained in Paragraph 111 of Plaintiffs'
10 Complaint.

11 112. Defendants deny the allegations contained in Paragraph 112 of Plaintiffs'
12 Complaint, including all subparts thereof.

13 113. Defendants deny the allegations contained in Paragraph 113 of Plaintiffs'
14 Complaint.

15 114. Defendants deny the allegations contained in Paragraph 114 of Plaintiffs'
16 Complaint.

17 **SECOND CAUSE OF ACTION**

18 **STRICT PRODUCT LIABILITY – FAILURE TO WARN**

19 115. Defendants incorporate by reference their responses to Paragraphs 1-114 of
20 Plaintiffs' Complaint as if fully set forth herein.

21 116. Defendants are without knowledge or information sufficient to form a belief as
22 to the truth of the allegations regarding the trade name of any inferior vena cava filter
23 implanted in Plaintiff Mary Duffie and, on that basis, deny them. By way of further response,
24 Defendants admit that Bard owns a facility where vena cava filters are manufactured and that
25 filters under the trademark G2® Filter System were manufactured at that facility. Defendants
26 further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and
27 that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter
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1 System. Defendants deny any remaining allegations contained in Paragraph 116 of Plaintiffs'
2 Complaint.

3 117. Defendants deny the allegations contained in Paragraph 117 of Plaintiffs'
4 Complaint.

5 118. The allegations contained in Paragraph 118 regarding Defendants' duty are
6 legal conclusions of law, and no answer is required. To the extent a response is required,
7 Defendants deny the allegations. Defendants deny the remaining allegations contained in
8 Paragraph 118 of Plaintiffs' Complaint.

9 119. Defendants deny the allegations contained in Paragraph 119 of Plaintiffs'
10 Complaint.

11 120. Defendants deny the allegations contained in Paragraph 120 of Plaintiffs'
12 Complaint.

13 121. Defendants deny the allegations contained in Paragraph 121 of Plaintiffs'
14 Complaint.

15 122. Defendants deny the allegations contained in Paragraph 122 of Plaintiffs'
16 Complaint.

17 123. Defendants deny the allegations contained in Paragraph 123 of Plaintiffs'
18 Complaint.

19 124. Defendants deny the allegations contained in Paragraph 124 of Plaintiffs'
20 Complaint.

21 125. Defendants deny the allegations contained in Paragraph 125 of Plaintiffs'
22 Complaint.

23 **THIRD CAUSE OF ACTION**

24 **STRICT PRODUCTS LIABILITY – DESIGN DEFECTS**

25 126. Defendants incorporate by reference their responses to Paragraphs 1-125 of
26 Plaintiffs' Complaint as if fully set forth herein.

127. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff Mary Duffie and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants deny any remaining allegations contained in Paragraph 127 of Plaintiffs' Complaint.

128. Defendants deny the allegations contained in Paragraph 128 of Plaintiffs' Complaint.

129. Defendants deny the allegations contained in Paragraph 129 of Plaintiffs' Complaint.

130. Defendants deny the allegations contained in Paragraph 130 of Plaintiffs' Complaint.

131. Defendants deny the allegations contained in Paragraph 131 of Plaintiffs' Complaint.

132. Defendants deny the allegations contained in Paragraph 132 of Plaintiffs' Complaint.

133. Defendants deny the allegations contained in Paragraph 133 of Plaintiffs' Complaint.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

134. Defendants incorporate by reference their responses to Paragraphs 1-133 of Plaintiffs' Complaint as if fully set forth herein.

135. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter

1 implanted in Plaintiff Mary Duffie and, on that basis, deny them. By way of further response,
 2 Defendants admit that Bard owns a facility where vena cava filters are manufactured and that
 3 filters under the trademark G2® Filter System were manufactured at that facility. Defendants
 4 further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and
 5 that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter
 6 System. Defendants deny any remaining allegations contained in Paragraph 135 of Plaintiffs'
 7 Complaint.

8 136. Defendants deny the allegations contained in Paragraph 136 of Plaintiffs'
 9 Complaint.

10 137. Defendants deny the allegations contained in Paragraph 137 of Plaintiffs'
 11 Complaint.

12 138. Defendants deny the allegations contained in Paragraph 138 of Plaintiffs'
 13 Complaint.

14 139. Defendants deny the allegations contained in Paragraph 139 of Plaintiffs'
 15 Complaint.

16 **FIFTH CAUSE OF ACTION**

17 **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

18 140. Defendants incorporate by reference their responses to Paragraphs 1-139 of
 19 Plaintiffs' Complaint as if fully set forth herein.

20 141. Defendants admit that Bard owns a facility where vena cava filters are
 21 manufactured (including filters under the trademark G2® Filter System) and further admit
 22 that BPV designs, sells, markets, and distributes inferior vena cava filters (including filters
 23 under the trademark G2® Filter System). Defendants deny that they made any warranties,
 24 express or otherwise, other than those expressly stated on the device, packaging, or
 25 instructions that accompanied the device. Defendants deny the remaining allegations
 26 contained in Paragraph 141 of Plaintiffs' Complaint.

1 142. Defendants deny the allegations contained in Paragraph 142 of Plaintiffs'
2 Complaint.

3 143. Defendants deny the allegations contained in Paragraph 143 of Plaintiffs'
4 Complaint.

5 144. Defendants deny the allegations contained in Paragraph 144 of Plaintiffs'
6 Complaint.

7 145. Defendants deny the allegations contained in Paragraph 145 of Plaintiffs'
8 Complaint, including all subparts thereof.

9 146. Defendants deny the allegations contained in Paragraph 146 of Plaintiffs'
10 Complaint.

11 147. Defendants deny the allegations contained in Paragraph 147 of Plaintiffs'
12 Complaint.

13 148. Defendants deny the allegations contained in Paragraph 148 of Plaintiffs'
14 Complaint.

15 149. Defendants deny the allegations contained in Paragraph 149 of Plaintiffs'
16 Complaint.

17 **SIXTH CAUSE OF ACTION**

18 **NEGLIGENT MISREPRESENTATION**

19 150. Defendants incorporate by reference their responses to Paragraphs 1-149 of
20 Plaintiffs' Complaint as if fully set forth herein.

21 151. Defendants deny the allegations contained in Paragraph 151 of Plaintiffs'
22 Complaint, including all subparts thereof.

23 152. Defendants deny the allegations contained in Paragraph 152 of Plaintiffs'
24 Complaint.

25 153. Defendants deny the allegations contained in Paragraph 153 of Plaintiffs'
26 Complaint.

1 154. Defendants deny the allegations contained in Paragraph 154 of Plaintiffs'
2 Complaint.

3 155. Defendants deny the allegations contained in Paragraph 155 of Plaintiffs'
4 Complaint.

5 156. Defendants deny the allegations contained in Paragraph 156 of Plaintiffs'
6 Complaint.

7 157. Defendants deny the allegations contained in Paragraph 157 of Plaintiffs'
8 Complaint.

9 158. Defendants deny the allegations contained in Paragraph 158 of Plaintiffs'
10 Complaint.

11 159. Defendants deny the allegations contained in Paragraph 159 of Plaintiffs'
12 Complaint.

13 160. Defendants deny the allegations contained in Paragraph 160 of Plaintiffs'
14 Complaint.

15 **LOSS OF CONSORTIUM CLAIM**

16 161. Defendants incorporate by reference their responses to Paragraphs 1-160 of
17 Plaintiffs' Complaint as if fully set forth herein.

18 162. Defendants are without knowledge or information sufficient to admit or deny
19 the allegations contained in Paragraph 162 of Plaintiffs' Complaint and, on that basis, deny
20 them.

21 163. Defendants deny the allegations contained in Paragraph 163 of Plaintiffs'
22 Complaint.

23 **PUNITIVE DAMAGES ALLEGATIONS**

24 164. Defendants incorporate by reference their responses to Paragraphs 1-163 of
25 Plaintiffs' Complaint as if fully set forth herein.

26 165. Defendants deny the allegations contained in Paragraph 165 of Plaintiffs'
27 Complaint.

1 166. Defendants deny the allegations contained in Paragraph 166 of Plaintiffs'
2 Complaint, including all subparts thereof.

3 167. Defendants deny the allegations contained in Paragraph 167 of Plaintiffs'
4 Complaint.

5 168. Defendants deny the allegations contained in Paragraph 168 of Plaintiffs'
6 Complaint.

7 **PRAYER FOR RELIEF**

8 Furthermore, responding to the unnumbered Paragraph, including sub-parts, following
9 the heading "PRAYER FOR RELIEF" and beginning "WHEREFORE," Defendants deny the
10 allegations contained in such Paragraph and all sub-parts thereof.

11 Defendants further deny each and every allegation not specifically admitted herein.

12 Defendants allege as affirmative defenses the following:

13 1. Plaintiffs' Complaint filed herein fails to state a claim or claims upon which
14 relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

15 2. The sole proximate cause of Plaintiffs' damages, if any were sustained, was the
16 negligence of a person or persons or entity for whose acts or omissions Defendants were and
17 are in no way liable.

18 3. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of
19 limitations and/or statute of repose.

20 4. If Plaintiffs have been damaged, which Defendants deny, any recovery by
21 Plaintiffs is barred to the extent Plaintiffs voluntarily exposed themselves to a known risk
22 and/or failed to mitigate their alleged damages. To the extent Plaintiffs have failed to mitigate
23 their alleged damages, any recovery shall not include alleged damages that could have been
24 avoided by reasonable care and diligence.

25 5. If Plaintiffs have been damaged, which Defendants deny, such damages were
26 caused by the negligence or fault of Plaintiffs.

1 6. If Plaintiffs have been damaged, which Defendants deny, such damages were
2 caused by the negligence or fault of persons and/or entities for whose conduct Defendants are
3 not legally responsible.

4 7. The conduct of Defendants and the subject product at all times conformed with
5 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, et seq., and other pertinent
6 federal statutes and regulations. Accordingly, Plaintiffs' claims are barred, in whole or in
7 part, under the doctrine of federal preemption, and granting the relief requested would
8 impermissibly infringe upon and conflict with federal laws, regulations, and policies in
9 violation of the Supremacy Clause of the United States Constitution.

10 8. If Plaintiffs have been damaged, which Defendants deny, such damages were
11 caused by unforeseeable, independent, intervening, and/or superseding events for which
12 Defendants are not legally responsible.

13 9. There was no defect in the product at issue with the result that Plaintiffs are not
14 entitled to recover against Defendants in this cause.

15 10. If there were any defect in the products – and Defendants deny that there were
16 any defects – nevertheless, there was no causal connection between any alleged defect and
17 the product on the one hand and any damage to Plaintiffs on the other with the result that
18 Plaintiffs are not entitled to recover against Defendants in this cause.

19 11. Plaintiffs' injuries, losses or damages, if any, were caused by or contributed to
20 by other persons or entities that are severally liable for all or part of Plaintiffs' alleged
21 injuries, losses or damages. If Defendants are held liable to Plaintiffs, which liability is
22 specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification,
23 either in whole or in part, from all persons or entities whose negligence or fault proximately
24 caused or contributed to cause Plaintiffs' alleged damages.

25 12. Plaintiffs' claims are barred to the extent that the injuries alleged in the
26 Complaint were caused by the abuse, misuse, abnormal use, or use of the product at issue in a
27 manner not intended by Defendants and over which Defendants had no control.
28

1 13. Plaintiffs' claims are barred to the extent that the injuries alleged in the
2 Complaint were caused by a substantial change in the product after leaving the possession,
3 custody, and control of Defendants.

4 14. Plaintiffs' breach of warranty claims are barred because: (1) Defendants did not
5 make any warranties, express or implied, to Plaintiffs; (2) there was a lack of privity between
6 Defendants and Plaintiffs; and (3) notice of an alleged breach was not given to the seller or
7 Defendants.

8 15. Plaintiffs' claims for breach of implied warranty must fail because the product
9 was not used for its ordinary purpose.

10 16. Defendants neither had nor breached any alleged duty to warn with respect to
11 the product, with the result that Plaintiffs are not entitled to recover in this cause.

12 17. Plaintiffs' claims are barred by Defendants' dissemination of legally adequate
13 warnings and instructions to learned intermediaries.

14 18. At all relevant times, herein, Plaintiffs' physicians were in the position of
15 sophisticated purchasers, fully knowledgeable and informed with respect to the risks and
16 benefits of the subject product.

17 19. If Plaintiffs' has been damaged, which Defendants deny, the actions of persons
18 or entities for whose conduct Defendants are not legally responsible and the independent
19 knowledge of these persons or entities of the risks inherent in the use of the product and other
20 independent causes, constitute an intervening and superseding cause of Plaintiffs' alleged
21 damages.

22 20. To the extent that injuries and damages sustained by Plaintiffs, as alleged in
23 Plaintiffs' Complaint, were caused directly, solely, and proximately by sensitivities, medical
24 conditions, and idiosyncrasies peculiar to Plaintiffs not found in the general public, they were
25 unknown, unknowable, or not reasonably foreseeable to Defendants.

26 21. Defendants believe, and upon that ground allege, that Plaintiffs were advised of
27 the risks associated with the matters alleged in Plaintiffs' Complaint and knowingly and
28

1 voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed
2 consent, release, waiver, or comparative fault, this conduct bars in whole or in part the
3 damages that Plaintiffs seek to recover herein.

4 22. At all relevant times during which the device at issue was designed, developed,
5 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
6 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
7 information, and instructions, all pursuant to generally recognized prevailing industry
8 standards and state-of-the-art in existence at the time.

9 23. Plaintiffs' claims are barred because Plaintiffs suffered no injury or damages as
10 a result of the alleged conduct and do not have any right, standing, or competency to maintain
11 claims for damages or other relief.

12 24. Plaintiffs' claims are barred, in whole or in part, by the doctrines of waiver,
13 estoppel, and/or laches.

14 25. If Plaintiffs suffered any damages or injuries, which are denied, Defendants
15 state that Plaintiffs' recovery is barred, in whole or in part, or subject to reduction, under the
16 doctrines of contributory and/or comparative negligence.

17 26. In the further alternative, and only in the event that it is determined that
18 Plaintiffs are entitled to recover against Defendants, recovery should be reduced in proportion
19 to the degree or percentage of negligence, fault or exposure to products attributable to
20 Plaintiffs, any other defendants, third-party defendants, or other persons, including any party
21 immune because bankruptcy renders them immune from further litigation, as well as any
22 party, co-defendant, or non-parties with whom Plaintiffs have settled or may settle in the
23 future.

24 27. Should Defendants be held liable to Plaintiffs, which liability is specifically
25 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiffs
26 from all collateral sources.

1 28. Plaintiffs' claims may be barred, in whole or in part, from seeking recovery
2 against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of
3 claims, and the prohibition on double recovery for the same injury.

4 29. The injuries and damages allegedly sustained by Plaintiffs may be due to the
5 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiffs,
6 over which Defendants had no control.

7 30. The conduct of Defendants and all activities with respect to the subject product
8 have been and are under the supervision of the Federal Food and Drug Administration
9 ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief,
10 is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

11 31. Defendants assert any and all defenses, claims, credits, offsets, or remedies
12 provided by the Restatements (Second and Third) of Torts and reserve the right to amend
13 their Answer to file such further pleadings as are necessary to preserve and assert such
14 defenses, claims, credits, offsets, or remedies.

15 32. The device at issue complied with any applicable product safety statute or
16 administrative regulation, and therefore Plaintiffs' defective design and warnings-based
17 claims are barred under the Restatement (Third) of Torts: Products Liability § 4, et seq. and
18 comments thereto.

19 33. Plaintiffs cannot show that any reasonable alternative design would have
20 rendered the G2® Filter inferior vena cava filter device as alleged in Plaintiffs' Complaint to
21 be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f, nor could
22 Defendants have known of any alternative design that may be identified by Plaintiffs.

23 34. The device at issue was not sold in a defective condition unreasonably
24 dangerous to the user or consumer, and therefore Plaintiffs' claims are barred under the
25 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and
26 comparable provisions of the Restatement (Third) of Torts (Products Liability).

1 35. At all relevant times during which the device at issue was designed, developed,
2 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
3 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
4 information, and instructions, all pursuant to generally recognized prevailing industry
5 standards and state-of-the-art in existence at the time.

6 36. Defendants specifically plead all affirmative defenses under the Uniform
7 Commercial Code (“UCC”) now existing or which may arise in the future, including those
8 defenses provided by UCC §§ 2-607 and 2-709.

9 37. Plaintiffs’ alleged damages, if any, should be apportioned among all parties at
10 fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors
11 Act.

12 38. No act or omission of Defendants was malicious, willful, wanton, reckless, or
13 grossly negligent, and, therefore, any award of punitive damages is barred.

14 39. To the extent the claims asserted in Plaintiffs’ Complaint are based on a theory
15 providing for liability without proof of defect and proof of causation, the claims violate
16 Defendants’ rights under the Constitution of the United States and analogous provisions of
17 the Georgia Constitution.

18 40. Regarding Plaintiffs’ demand for punitive damages, Defendants specifically
19 incorporate by reference any and all standards of limitations regarding the determination
20 and/or enforceability of punitive damages awards that arose in the decisions of *BMW of*
21 *No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool*
22 *Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct.
23 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S.
24 June 25, 2008) and their progeny as well as other similar cases under both federal and state
25 law.

26 41. Plaintiffs’ claims for punitive or exemplary damages violate, and are therefore
27 barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of
28

1 the United States of America, and similar provisions of the Georgia Constitution, on grounds
2 including the following:

- 3 (a) it is a violation of the Due Process and Equal Protection Clauses of the
4 Fourteenth Amendment of the United States Constitution to impose punitive
5 damages, which are penal in nature, against a civil defendant upon the plaintiff
6 satisfying a burden of proof which is less than the “beyond a reasonable doubt”
7 burden of proof required in criminal cases;
- 8 (b) the procedures pursuant to which punitive damages are awarded may result in
9 the award of joint and several judgments against multiple defendants for
10 different alleged acts of wrongdoing, which infringes upon the Due Process and
11 Equal Protection Clauses of the Fourteenth Amendment of the United States
12 Constitution;
- 13 (c) the procedures to which punitive damages are awarded fail to provide a
14 reasonable limit on the amount of the award against Defendants, which thereby
15 violates the Due Process Clause of the Fourteenth Amendment of the United
16 States Constitution;
- 17 (d) the procedures pursuant to which punitive damages are awarded fail to provide
18 specific standards for the amount of the award of punitive damages which
19 thereby violates the Due Process Clause of the Fourteenth Amendment of the
20 United States Constitution;
- 21 (e) the procedures pursuant to which punitive damages are awarded result in the
22 imposition of different penalties for the same or similar acts, and thus violate
23 the Equal Protection Clause of the Fourteenth Amendment of the United States
24 Constitution;
- 25 (f) the procedures pursuant to which punitive damages are awarded permit the
26 imposition of punitive damages in excess of the maximum criminal fine for the
27 same or similar conduct, which thereby infringes upon the Due Process Clause
28

of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;

(h) the award of punitive damages to the plaintiffs in this action would constitute a deprivation of property without due process of law; and

(i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

42. Defendants expressly reserve the right to raise as an affirmative defense that Plaintiffs have failed to join all parties necessary for a just adjudication of this action, should discovery reveal the existence of facts to support such defense.

43. The design complained of in Plaintiffs' Complaint, the alleged defects of the product, and/or any alternative design claimed by Plaintiffs were not known and, in light of the existing, reasonably-available scientific and technological knowledge, could not have been known at the time the product at issue was designed, manufactured, and sold. Any alleged alternative design was not scientifically or technologically feasible or economically practical.

44. To the extent the Complaint alleges misrepresentation and fraud, these allegations do not comply with the requisite of particularity under applicable procedural rules and/or law.

45. Defendants reserve the right to raise such other affirmative defenses as may be available or apparent during discovery or as may be raised or asserted by other defendants in this case. Defendants have not knowingly or intentionally waived any applicable affirmative defense. If it appears that any affirmative defense is or may be applicable after Defendants have had the opportunity to conduct reasonable discovery in this matter, Defendants will assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

REQUEST FOR JURY TRIAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

WHEREFORE, Defendants aver that Plaintiffs is not entitled to the relief demanded in the Complaint, and these Defendants, having fully answered, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

s/Richard B. North, Jr.
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**Attorney for Defendants C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.**

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on October 26, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

s/Richard B. North, Jr.
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